Complete Summary

GUIDELINE TITLE

NKF-K/DOQI clinical practice guidelines for hemodialysis adequacy: update 2000.

BIBLIOGRAPHIC SOURCE(S)

NKF-K/DOQI clinical practice guidelines for hemodialysis adequacy: update 2000. Am J Kidney Dis 2001 Jan; 37(1 Suppl 1): S7-S64. [259 references]

COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

End-stage renal disease (ESRD)

GUIDELINE CATEGORY

Treatment

CLINICAL SPECIALTY

Family Practice Internal Medicine Nephrology Pediatrics

INTENDED USERS

Advanced Practice Nurses Allied Health Personnel Clinical Laboratory Personnel Health Care Providers Health Plans Nurses Patients Physician Assistants Physicians

GUIDELINE OBJECTIVE(S)

- 1. The primary objective of the National Kidney Foundation-Kidney Disease Outcomes Quality Initiative is to improve patient outcomes and survival by providing recommendations for optimal clinical practices, thereby increasing the efficiency of patient care, and positively impacting patient outcomes.
- 2. To review the literature that has become available since 1997. Based upon this review, develop updates and supplements as needed.
- 3. To identify barriers to the acceptance and implementation of guidelines.
- 4. To develop strategies for enhancing the implementation of clinical practice guidelines for hemodialysis adequacy.

TARGET POPULATION

These guidelines apply to all adult and pediatric hemodialysis patients with end-stage renal disease (ESRD) and negligible renal function (glomerular filtration rate <5 mL/min) who receive outpatient hemodialysis three times per week. These guidelines are not applicable to patients who undergo hemodialysis two times per week, hospitalized patients receiving hemodialysis, patients with residual glomerular filtration rate (GFR) >5mL/min, or patients with a reasonable presumption of recovery of renal function. The guidelines also may not be applicable to hemodialysis patients outside of the United States and the American Trust Territories (Puerto Rico, Guam, American Samoa, and Saipan) because of substantial international differences in patient mix, processes of patient care, and reimbursement mechanisms for the care of end-stage

INTERVENTIONS AND PRACTICES CONSIDERED

- Measurement of hemodialysis adequacy
- Hemodialysis dose
- Blood urea nitrogen (BUN) sampling
- Hemodialyzer reprocessing and reuse
- Hemodialysis dose troubleshooting
- Maximizing patient compliance to the hemodialysis prescription

MAJOR OUTCOMES CONSIDERED

- Morbidity and mortality among end-stage renal disease patients on hemodialysis
- Indicators of hemodialysis adequacy
- Frequency of intradialytic complications such as symptomatic hypotension and cramps

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

From the 1997 Guideline

Initial literature searches

With the help of a former senior subject heading specialist from the National Library of Medicine, project staff performed initial searches of four computerized bibliographic databases: The National Library of Medicine's MEDLINE(R), EMBASE, SciSearch(R), and BIOSIS(R) Previews. Staff used free text terms and controlled vocabulary, such as the NLM's Medical Subject Heading (MeSH). Searches were both general in scope for high sensitivity in identification of pertinent literature (for example, a search related to vascular access and end stage renal disease) and specific to preliminary topics selected by the Work Group Chairs for precision (for example, prevention of particular types of complications). In total 5,746 articles were identified by the initial searches.

Work Group Chairs identified the most important papers related to their topic. These papers were retrieved.

Records retrieved from the searches were transferred into topic-specific databases using Reference Manager, a commercial bibliography management software package. Staff used Reference Manager to maintain and track records throughout the process.

Mock guidelines, rationales, and question lists

To enhance both the sensitivity and specificity of the National Kidney Foundation-Kidney Disease Outcomes Quality Initiative literature review, a systematic process was employed at the July 1995 Work Group meeting to define the questions to be addressed in the literature review. The process involved three sequential tasks. First, each Work Group developed a set of "mock guideline" statements that reflected the types of recommendations they would ultimately like to develop. For example, a mock guideline related to peritoneal dialysis adequacy was:

The dose of peritoneal dialysis that is actually delivered should be measured using (method).

Next, each Work Group developed a draft chain of logic or rationale, which delineated the logical sequence of issues and assumptions that would need to be addressed in order to come to a recommendation on each guideline topic.

For example, the draft rationale related to the preceding mock guideline was:

1.	and are currently used to measure peritoneal dialysis dose.
2.	is more strongly associated with patient morbidity and mortality than
	is
3.	In addition, is a more reproducible measure than
4.	In light of these considerations, is the preferred approach for
	measuring peritoneal dialysis dose.

Finally, each Work Group worked with staff to develop a question list to be addressed in the literature review. The answers to these questions would fill in each link in the chain of logic, which could then be used to develop the practice recommendations. Specific questions for the example above were:

- 1. What is the association between total weekly urea clearance x time normalized by total body water, the volume of distribution of urea (Kt/V_{urea}) and patient mortality?
- 2. What is the association between weekly creatinine clearance and patient mortality?
- 3. Does knowledge of weekly creatinine clearance provide any additional information regarding expected patient survival than does knowledge of weekly Kt/V_{urea}?

Detailed literature abstraction forms were then developed to help Work Group members extract the answers to the questions from the literature review. To the Committee's knowledge, this is the first time such an approach has been employed to focus a guideline development literature review effort. In previous guideline development efforts, expert panels have typically developed a list of questions to be addressed in the literature review without explicitly articulating the types of guideline statements they would ultimately like to issue. The result has often been that, after completing the literature review, a guideline development panel has found that it failed to address in the literature review several pertinent issues that needed to be considered to develop particular practice guidelines. By devoting considerable thought at the outset to "mock guideline" statements and the associated chain of logic that would underlie each, we were able to conduct a comprehensive, yet efficient literature review.

Complete supplemental and update searches

After determining that many pertinent papers were not identified during initial computerized searches, the Chair of each Work Group worked with staff to design supplemental computerized searches. These supplemental searches targeted the authors of important papers that had been missed and additional key words. All searches were updated through approximately September 1995. Additional pertinent articles identified by Work Group members and peer reviewers were added through June 1997.

Screening the literature

Work Group members performed the literature review. This entailed screening the literature for pertinence and then conducting a structured review.

The initial computerized searches of the literature identified 5,746 articles. Supplemental and update searches identified 5,065 more articles, and additions

by Work Group members and staff yielded an additional 818 articles for a total of 11,629. To ensure that the detailed literature review process was efficient, a two-step screening process was employed to identify articles that would undergo a structured review.

In the first screen, each Work Group Chair reviewed a list of titles and abstracts obtained from the search of computerized literature databases. The Work Group Chairs were asked to eliminate articles that were clearly not relevant to the questions to be addressed in their Work Group's literature review. Work Group Chairs were instructed not to eliminate articles for any other reason, such as a belief that the journal in which the article was published was not highly regarded. Staff retrieved the full text of articles that passed the first screen.

The full text of articles that passed this first screen were then divided among Work Group members by the Work Group Chair. Work Group members were asked to read these articles and determine whether each was pertinent to the questions being addressed in the literature review or the guideline topic in general. Work Group Chairs typically assigned articles to individual Work Group members based on their expertise. During this pertinence review, two Work Group members reviewed each article and categorized articles as "key," "pertinent, but not key," or "not pertinent." Key articles were articles thought to be particularly important to the development of a particular guideline. Articles identified as either "key" or "pertinent, but not key" by at least one of the two Work Group members were then moved on to the next stage of the process, the structured review.

From the 2000 Update

Rather than conduct an exhaustive search of the articles published since 1996, the Work Group adopted a "top-down" approach, whereby the experts on the Work Groups scanned the literature and selected pertinent articles. These articles were subjected to external review, and the Work Groups selected a final list to undergo structured review.

NUMBER OF SOURCE DOCUMENTS

Summary of Literature Review for Hemodialysis Adequacy from the 1997 Guideline:

- Total articles identified (searches, later additions) = 2,481
- First screen: articles retrieved in full text = 635
- Second screen: articles that underwent structured review = 319
- Total articles cited in final report = 185

Number of Source Documents from the 2000 Update:

The update process for the four original Kidney Disease Outcomes Quality Initiative guidelines focused on a total of 85 articles published since 1996 and considered to be potentially relevant by the Work Group. Of these, 57 were subjected to structured review according to published Disease Outcomes Quality Initiative methods. The number of source documents for each clinical practice guideline was not delineated.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE FVI DENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

In addition to the structured review of the clinical content of pertinent articles that was performed as part of the Disease Outcomes Quality Initiative Guideline development process, a structured assessment of the methodologic rigor of pertinent articles was performed. In this assessment, four tasks were performed. First, the type of study design used in the study was defined and used to assign the article to a United States Preventive Services Task Force Quality of Evidence Category (see Table 3 in the companion document to the original guideline titled "Methods Used to Evaluate the Quality of Evidence Underlying the National Kidney Foundation-Dialysis Outcomes Quality Initiative Clinical Practice Guidelines: Description, Findings and Implications"*). Second, for each article that underwent a methods review, up to 24 aspects of study design (the exact number depended on the type of study being reviewed) were rated as being fully, partially, or not fulfilled (see Table 4 in the companion document to the original guideline titled "Methods Used to Evaluate the Quality of Evidence Underlying the National Kidney Foundation-Dialysis Outcomes Quality Initiative Clinical Practice Guidelines: Description, Findings and Implications"*). The sum of the scores for those aspects of study design that applied to a given article was then divided by the number of applicable questions, yielding a methods score for the article between 0 and 1. Third, the overall quality of each article that underwent a methods review was rated as excellent, very good, good, fair, or poor based on a global subjective judgment made by the methods reviewer. Finally, based on the results of these ratings, each article was assigned a grade of "a", "b", or "c". An "a" grade was assigned if at least 50% of the answers to the methods review questions that applied to the article (see Table 4 in the companion document to the original guideline titled "Methods Used to Evaluate the Quality of Evidence Underlying the National Kidney Foundation-Dialysis Outcomes Quality Initiative Clinical Practice Guidelines: Description, Findings and Implications"*) were answered "yes". A grade of "b" was assigned when less than 50% of the answers to methods review questions that applied to the article were answered "yes". A "c" grade was assigned to an article when at least one of the following four criteria applied to the article: (1) important demographic and/or prognostic characteristics of the enrolled sample were not described. (2) outcome measurements were not made in a similar fashion in the patient groups being compared, (3) the article received a global subjective quality rating of poor, or (4) the article was a case report. All methods reviews were performed by experienced individuals with masters or doctoral degrees in public health, epidemiology, biostatistics, or a similar discipline.

^{*} See the companion document to the original guideline: Steinberg EP, Eknoyan G, Levin NW, et al. "Methods Used to Evaluate the Quality of Evidence Underlying the National Kidney Foundations-Dialysis Outcomes Quality Initiative Clinical Practice Guidelines: Description, Findings, and Implications." Am J Kidney Dis 2000 Jul; 36(1):1-11. Available from the American Journal of Kidney Diseases Web site.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Data Abstraction

Three types of data abstraction forms were used in the review process: (1) a content abstraction form designed for use in abstracting clinical data pertaining to each literature review question; (2) a methods assessment form designed to provide a rough assessment of the methodologic rigor of a paper; and (3) a detailed methods review form designed to assess the methodologic rigor of pivotal or controversial papers.

Staff used the detailed list of questions produced by the Work Groups to develop clinical content abstraction forms for each Work Group. Each detailed question posed by the Work Group was decomposed into subquestions that would capture pertinent data from studies that could vary tremendously in design, content, and presentation of data. Reviewers were asked to summarize any pertinent data from each article that were not addressed by the form and to provide comments on the overall quality of the paper. Renal fellows then pilot-tested the forms using articles identified in the search. Staff conducted conference calls with each topic-specific group of fellows following the pilot-test and reviewed issues and problems with the draft forms. In addition, feedback from Work Group Chairs was incorporated into the draft forms before finalizing them.

Structured review

Articles identified as "key" or "pertinent, but not key," underwent structured review for both clinical content and methodologic rigor. Work Group members reviewed all "key" articles. This ensured that clinical experts reviewed the most important papers, and helped inform Work Group members of the content and quality of the papers. "Pertinent, but not key" articles were reviewed by renal fellows assigned to each Work Group.

Pertinent papers with primary or secondary data also underwent a methods review which was performed by staff with training in biostatistics and/or epidemiology. In the end, 1,447 articles, or 13 percent of those identified initially, were subjected to structured review.

Synthesis

The results of the literature review were compiled and synthesized when responses lent themselves to synthesis. Responses to qualitative questions were reported verbatim in tabular format. Quantitative data were presented in tabular format, and aggregated when possible. Since most studies did not report comparable data, aggregation was possible in only a limited number of cases.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Work Groups discussed the available evidence during two meetings and formulated draft guidelines and a rationale for each. In the rationale, the evidentiary basis (specific empirical data or expert opinion) for each recommendation was made explicit. Consensus was not forced. Rather, if divergent opinions emerged, the different viewpoints, and the basis for the divergent opinions, were recorded.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

When all components of the rationale for a guideline are based on published evidence, the guideline has been labeled "Evidence."

When some or all components of a rationale are based on opinion, the guideline has been labeled "Opinion."

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

As was the case with the initial guidelines, the current guideline updates were subjected to a three stage review process.

Stage One

They were presented first to the National Kidney Foundation-Kidney Disease Outcomes Quality Initiative Steering Committee and revised in response to the comments received.

Stage Two

In the second stage, the Kidney Disease Outcomes Quality Initiative Advisory Board, along with other experts in the field, provided comments. After considering these, the Work Group produced a third draft of the guidelines.

Third Stage

In the final stage, this draft was made available for public review and comment by all interested parties, including end stage renal disease networks, professional and patient associations, dialysis providers, government agencies, product manufacturers, managed care groups, and individuals. The comments received

were reviewed and, where appropriate, incorporated in the final version of the updated guidelines.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Evidentiary Basis For Recommendations:

When all components of the rationale for a guideline are based on published evidence, the guideline has been labeled "Evidence."

When some or all components of a rationale are based on opinion, the guideline has been labeled "Opinion."

- 1. Regular Measurement of Delivered Dose of Hemodialysis (Evidence). The dialysis care team should routinely measure and monitor the delivered dose of hemodialysis.
- 2. Method of Measurement of Delivered Dose of Hemodialysis (Evidence). The delivered dose of hemodialysis in adult and pediatric patients should be measured using formal urea kinetic modeling, employing the single-pool, variable-volume model.
- 3. Uniformity of Method of Measurement (Opinion). All patients receiving hemodialysis in the same dialysis facility should have the delivered dose of hemodialysis measured using the same method.
- 4. Minimum Delivered Dose of Hemodialysis (Adults-Evidence, Children-Opinion). The dialysis care team should deliver a fractional clearance of urea as a function of its distribution volume (Kt/V) of at least 1.2 (single-pool, variable-volume) for both adult and pediatric hemodialysis patients. For those using the urea reduction ratio, the delivered dose should be equivalent to a Kt/V of 1.2, i.e., an average urea reduction ratio of 65%. Urea reduction ratio can vary substantially as a function of fluid removal.
- 5. Prescribed Dose of Hemodialysis (Opinion). To prevent the delivered dose of hemodialysis from falling below the recommended minimum dose, the prescribed dose of hemodialysis should be Kt/V 1.3. In terms of urea reduction ratio, a Kt/V of 1.3 corresponds to an average urea reduction ratio of 70%, but the urea reduction ratio corresponding to a Kt/V of 1.3 can vary substantially as a function of ultrafiltration.
- 6. Frequency of Measurement of Hemodialysis Adequacy (Opinion). The delivered dose of hemodialysis should be measured at least once a month in all adult and pediatric hemodialysis patients. The frequency of measurement of the delivered dose of hemodialysis should be increased when:
 - Patients are noncompliant with their hemodialysis prescriptions (missed treatments, late for treatments, early sign-off from hemodialysis treatments, etc.);
 - 2. Frequent problems are noted in delivery of the prescribed dose of hemodialysis (such as variably poor blood flows, or treatment interruptions because of hypotension or angina pectoris);
 - 3. Wide variability in urea kinetic modeling results is observed in the absence of prescription changes; and/or
 - 4. The hemodialysis prescription is modified.

- 7. Blood Urea Nitrogen (BUN) Sampling (Evidence). Pre-dialysis and post-dialysis blood samples for measurement of blood urea nitrogen levels must be drawn at the same hemodialysis session. The same machine should be used for estimation of both samples.
- 8. Acceptable Methods for Blood Urea Nitrogen Sampling (Evidence). Blood samples for blood urea nitrogen measurement must be drawn in a particular manner. Pre-dialysis blood urea nitrogen samples should be drawn immediately prior to dialysis, using a technique that avoids dilution of the blood sample with saline or heparin. Post-dialysis blood urea nitrogen samples should be drawn using the Slow Flow/Stop Pump Technique that prevents sample dilution with recirculated blood and minimizes the confounding effects of urea rebound.
- 9. Standardization of Blood Urea Nitrogen Sampling Procedure (Opinion). Hemodialysis facilities should adopt a single blood urea nitrogen sampling method. If several different methods are used, the sampling method should be routinely recorded. The sampling method used for a given patient should remain consistent. The pre- and post-dialysis blood urea nitrogen samples for a given patient should be processed in the same batch analysis at the laboratory.
- 10. Use of the Association for the Advancement of Medical Instrumentation (AAMI) Standards and Recommended Practices for Hemodialyzer Reprocessing (Opinion). When hemodialyzers are reused, they should be reprocessed following the Association for the Advancement of Medical Instrumentation Standards and Recommended Practices for Reuse of Hemodialyzers, with the exception of the Advancement of Medical Instrumentation guideline regarding baseline measurement of the total cell volume. (See Guideline 11, below, titled "Baseline Measurement of Total Cell Volume").
- 11. Baseline Measurement of Total Cell Volume (Evidence). If a hollow-fiber dialyzer is to be reused, the total cell volume of that hemodialyzer should be measured prior to its first use. Batch testing and/or use of an average total cell volume for a group of hemodialyzers is not an acceptable practice.
- 12. Monitoring Total Cell Volume (Evidence). During each reprocessing, the total cell volume of reused dialyzers should be checked.
- 13. Minimum Required Total Cell Volume (Opinion). Dialyzers having a total cell volume <80% of original measured value should not be reused.
- 14. I nadequate Delivery of Hemodialysis (Opinion). If the delivered Kt/V falls below 1.2, or the urea reduction ratio declines to <65%, on a single determination, at least one of the following actions should be performed:
 - Investigate potential errors in the delivery of the prescribed hemodialysis dose (refer to the original guideline for a detailed discussion of error analysis for deficiencies in delivered Kt/V or urea reduction ratio);
 - 2. Empirically increase the prescribed dose of hemodialysis; and/or
 - 3. Suspend use of the reprocessed hollow-fiber hemodialyzer.

The impact of these corrective interventions should be followed by performing more frequent measurements of Kt/V or urea reduction ratio.

15. Optimizing Patient Comfort and Compliance (Opinion). Without compromising the delivered dose of hemodialysis, efforts should be undertaken to modify the hemodialysis prescription to prevent the occurrence

- of intradialytic symptoms that adversely affect patient comfort and adherence.
- 16. Strategies to Minimize Hypotensive Symptoms (Evidence). Without compromising the delivered dose of hemodialysis, efforts should be undertaken to minimize intradialytic symptoms that compromise the delivery of adequate hemodialysis, like hypotension and cramps. These efforts may include one or more of the following:
 - 1. Avoid excessive ultrafiltration:
 - 2. Slow the ultrafiltration rate;
 - 3. Perform isolated ultrafiltration;
 - 4. Increase the dialysate sodium concentration:
 - 5. Switch from acetate to bicarbonate-buffered dialysate;
 - 6. Reduce the dialysate temperature;
 - 7. Administer midodrine predialysis;
 - 8. Correction of anemia to the range recommended by the <u>National Kidney Foundation-Kidney Disease Outcomes Quality Initiative Anemia Guidelines</u>; and/or
 - 9. Administer supplemental oxygen.

CLINICAL ALGORITHM(S)

An error analysis algorithm for deficiencies in delivered Kt/V or urea reduction ratio is provided in the guideline.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Evidentiary Basis for Guidelines

The National Kidney Foundation-Kidney Disease Outcomes Quality Initiative guidelines were developed using an evidence-based approach similar to the one used by the Agency for Healthcare Research and Quality (AHRQ) (formerly the Agency for Health Care Policy and Research [AHCPR]). That is, before formulating recommendations, the Work Groups reviewed all published evidence pertinent to the topics being considered, and critically appraised the quality and strength of that evidence. For many issues that the National Kidney Foundation-Kidney Disease Outcomes Quality Initiative Work Groups chose to address, there either was no pertinent literature available, or available evidence was flawed or weak. As a result, in many instances the Work Groups formulated their recommendations based on the opinions of the Work Group members and comments received from the peer reviewers. In all instances, the Work Groups have documented the rationale for their recommendations. That is, they have articulated each link in the chain of logic they used as the evidentiary or opinion-related basis for their recommendation. This approach will help readers of the National Kidney Foundation-Kidney Disease Outcomes Quality Initiative guidelines determine the quantity and quality of evidence underlying each recommendation.

Although some of the National Kidney Foundation-Kidney Disease Outcomes Quality Initiative guidelines are clearly based entirely on evidence or entirely on opinion, many are based in part on evidence and in part on opinion. Such "hybrid" guidelines arise when some (or even most) of the links in the chain of logic underlying a guideline are based on empirical evidence, but some (that is, at least one) are based on opinion. The opinion of the Work Group members can enter the chain of logic that supports a guideline either to fill in a gap in available evidence on some scientific or clinical issue, or in the form of a value judgment regarding what they feel is appropriate clinical practice based on available evidence. Thus, many opinion-based guidelines may have substantial empirical evidence underlying them.

To help readers determine the basis for each guideline, the Work Groups have provided their rationale for each guideline. When all components of the rationale for a guideline are based on published evidence, the guideline has been labeled "Evidence." When some or all components of a rationale are based on opinion, the guideline has been labeled "Opinion."

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Decreased morbidity and mortality associated with end stage renal disease due to delivery of adequate hemodialysis.

POTENTIAL HARMS

Intradialytic complications include symptomatic hypotension and cramps.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

From the 1997 Guideline

- 1. These guidelines are based upon the best information available at the time of publication. They are designed to provide information and assist decision making. They are not intended to define a standard of care, and should not be construed as one. Neither should they be interpreted as prescribing an exclusive course of management. Variations in practice will inevitably and appropriately occur when clinicians take into account the needs of individual patients, available resources, and limitations unique to an institution or type of practice. Every health-care professional making use of these guidelines is responsible for evaluating the appropriateness of applying them in the setting of any particular clinical situation.
- 2. There are few reports in the medical literature of studies involving pediatric hemodialysis patients, and no data on outcomes as a function of hemodialysis dose in children. Previous efforts to develop guidelines for hemodialysis, including the Renal Physicians Association's guideline titled "Clinical Practice Guideline on Adequacy of Hemodialysis," did not address pediatric patients. The Hemodialysis Adequacy Work Group recognized the paucity of data on adequacy of hemodialysis in pediatric patients, but decided that is was desirable and possible to extend the guideline development process to

children. All available pediatric hemodialysis literature was reviewed; where pediatric data were lacking, the Work Group extrapolated from adult patient data. The Work Group recommends that a prospective, multi-center study of the effects of dialysis dose on outcomes in pediatric dialysis patients be undertaken.

From the 2000 Update

- 1. While extensive effort has gone into the guideline development process, and careful attention has been paid to detail and scientific rigor, it is absolutely essential to emphasize that these documents are guidelines, not standards or mandates. Each recommendation in the guidelines is accompanied by a rationale, enabling caregivers of patients with chronic kidney disease to make informed decisions about the proper care plan for each individual patients. Variations in practice are expected and can be appropriate.
- 2. The updated hemodialysis adequacy guidelines continue not to include all topics relevant to the global concept of hemodialysis adequacy. Topics not covered include the flux of large molecular weight solutes, membrane biocompatibility, appropriate timing for the initiation of hemodialysis, interplay between hemodialysis dose and nutrition, and the affect of hemodialysis dose and patients' quality of life and rehabilitation. Some of these topics are discussed in other Kidney Disease Outcomes Quality Initiative guidelines (that is, nutrition in the "Clinical Practice Guidelines for Nutrition in Patients with Chronic Renal Failure;" timing of the initiation of dialysis in the "Clinical Practice Guidelines on Peritoneal Dialysis Adequacy").

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

National Kidney Foundation-Kidney Disease Outcomes Quality Initiative Implementation Planning

Based on broad-based input and careful thought, the National Kidney Foundation-Kidney Disease Outcomes Quality Initiative leadership has decided to undertake three types of activities to promote implementation of its recommendations.

- Translating recommendations into practice. National Kidney Foundation-Kidney Disease Outcomes Quality Initiative will develop core patient and professional education programs and tools to facilitate the adoption of their recommendations.
- Building commitment to reducing practice variations. National Kidney Foundation-Kidney Disease Outcomes Quality Initiative will work with providers and insurers to clarify the need for and the benefits of changes in practice patterns and to encourage the adoption of the guidelines.
- Evaluation. National Kidney Foundation-Kidney Disease Outcomes Quality Initiative will develop performance measures that can be used to assess compliance with the Disease Outcomes Quality Initiative practice guidelines. In addition, the association between compliance with the Disease Outcomes Quality Initiative guidelines and patient outcomes will be evaluated in an effort to validate and improve the guidelines over time.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

NKF-K/DOQI clinical practice guidelines for hemodialysis adequacy: update 2000. Am J Kidney Dis 2001 Jan; 37(1 Suppl 1): S7-S64. [259 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1997 (updated 2000)

GUIDELINE DEVELOPER(S)

National Kidney Foundation - Disease Specific Society

SOURCE(S) OF FUNDING

The National Kidney Foundation-Kidney Disease Outcomes Quality Initiative (NKF-K/DOQI) is supported by Amgen, Inc., Founding and Principal Sponsor of K/DOQI and Luitpold Pharmaceuticals. Implementation of the K/DOQI guidelines is supported by Watson Pharmaceuticals, Inc., Nephrology Division (formerly Schein Pharmaceuticals, Inc.).

GUI DELI NE COMMITTEE

NKF-K/DOQI (National Kidney Foundation-Kidney Disease Outcomes Quality Initiative) Hemodialysis Adequacy Working Group

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Hemodialysis Adequacy Work Group Members: William Owen, Jr., MD, Work Group Chair; Jimmy Roberts, MD, Work Group Vice-Chair; Steven Alexander, MD; David Cohen, MD, PhD; William Harmon, MD; Todd Ing, MD; Judith Kari, MSW,

LICSW; Marcia Keen, PhD, RN; Karren King, MSW, ACSW, LCSW; Joseph Letteri, MD; A. Peter Lundin, MD; Anthony Messana, BSc; Jean Nardini, RN, MSN, CNN; Keith Norris, MD; Gigi Plitoski

K/DOQI Co-Chairs: Garabed Eknoyan, MD; Nathan W. Levin, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All Work Group members completed a disclosure statement certifying that any potential conflict of interest would not influence their judgment or actions concerning the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF-K/DOQI).

A. Peter Lundin, MD, FACP, reported an affiliation with Brooklyn Home Dialysis Training Center.

GUIDELINE STATUS

This is the current release of the guideline. It updates a previously issued version of the guideline (Clinical practice guidelines for hemodialysis adequacy. New York [NY]: National Kidney Foundation; 1997. 158 p. [Dialysis outcomes quality initiative (DOQI)]).

GUIDELINE AVAILABILITY

Electronic copies: Available from the National Kidney Foundation (NKF) Web site.

Print copies: Available from NKF, 30 East 33rd St., New York, NY 10016. These guidelines are also available on CD-ROM from NKF.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Owen WF. Hemodialysis adequacy. Executive summary. 2001. Available from the National Kidney Foundation (NKF) Web site.
- Steinberg EP, Eknoyan G, Levin NW, Eschbach JW, Golper TA, Owen WF, Schwab S. Methods used to evaluate the quality of evidence underlying the National Kidney Foundation-Dialysis Outcomes Quality Initiative clinical practice guidelines: description, findings and implications. Am J Kidney Dis 2000 Jul; 36(1):1-11.
- Eknoyan G, Levin NW, Eschbach JW, Golper TA, Owen WF Jr, Schwab S, Steinberg EP. Continuous quality improvement: DOQI becomes K/DOQI and is updated. National Kidney Foundation's Dialysis Outcomes Quality Initiative. Am J Kidney Dis 2001 Jan; 37(1):179-94. Available from the NKF Web site.

Print copies: Available from NKF, 30 East 33rd St., New York, NY 10016.

PATIENT RESOURCES

The following patient information is available.

- Getting the most from your treatment. What you need to know about hemodialysis. New York (NY): National Kidney Foundation (NKF), 1998.
- A pamphlet called "Nutrition and Hemodialysis". New York (NY): NKF, 1998.

Print copies: Available from NKF, 30 East 33rd St., New York, NY 10016.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was completed by ECRI on September 1, 2001. The information was verified by the guideline developer as of November 19, 2001.

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